201-14159

Chris Ford <c.ford@cardolite.com> on 12/20/2002 03:12:07 PM

To: oppt.ncic@epamail.epa.gov
cc:

Subject: Revised test plan and robust summary for cashew nutshell liquid, CAS# 8007-24-7

In response to the EPA's comments of November 7, 2002 on the robust summaries and test plan for Cashew Nutshell Liquid, attached is the revised Chemical Right-to Know HPV Challenge Program submission
for cashew nutshell liquid, CAS # 8007-24-7. This includes a revised cover letter, test plan, and robust summaries for the plan.

Please let me know if you have any questions regarding this.

Would you please reply with a confirmation that this information has been received.

Best regards,
Chris Ford
Cardolite Corporation
500 Doremus Avenue
Newark, N.J. 07105

Tel.# 973-344-5015 x121


Revised Test Plan.


Revised Human Gentox in vitro (A


Revised Human Gentox in vitro (Chromosomal a


Revised Human Gentox in vitro (HGPRT Forward muta


revised Environ Biodegradati


Revised Submission cover let

201-14159

Cardolite Corporation
500 Doremus Avenue
Newark, N.J. 07105
Tel.# 973-344-5015 x121

23 December 2002

Ms. Christie Whitman, Administrator
US Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

Re: Revised Chemical Right- to Know HPV Challenge Program Submission

Dear Ms. Whitman:

In November 2002, Cardolite Corporation, Inc. (CCI) received EPA comments on the test plan and supporting robust summaries for Cashew Nut Shell Liquid (CAS RN 8007- 24-7) which had been submitted to EPA on June 5, 2002 under the HPV Challenge Program. CCI also received comments from Environmental Defense (ED) and Physicians Committee for Responsible Medicine (PCRM).

In the interests of shar ing comments and communicating our intent with interested stakeholders, CCI is providing this single response to those parties who provided comments. Attached are the revised test plan, and robust summaries.

General Comments

ED suggested it would be useful to include more information on the composition of distilled CNSL.

Response: The test plan will be modified to include this information.

Physicochemical properties and Environmental Fate

Vapor pressure: EPA calculated a vapor pressure range of 1. 47x10-7 – 1.7x10-4 Pa. CCI calculated a vapor pressure of less than 2x10- 5 Pa. In view of the uncertainty in the calculated value, EPA requested that CCI measure the vapor pressure of CNSL.

Response: CCI will measure the vapor pressure of CNSL using OEC D Guideline 104.

Photodegradation: EPA believes that, based on the estimated values for vapor pressure, CNSL is a semi-volatile organic and can exist partially as vapor or adsorbed to particles and have requested that CCI provide estimated data for both cardanol and cardol.

Response: CCI will provide estimated data using AOPWIN to fulfil this endpoint.

Biodegradation: EPA requested that CCI tested CNSL for ready biodegradability following ECD Guideline 301, stating that the reported study included a preacclimation step.

Response: The reported study did not include a preacclimation step. Examination of the biodegradation curve shows that the substance met the 10- day window and can be considered to be ready biodegradable.

The robust summary will be updat ed to include this information. No further testing will be performed at this time.

Fugacity: EPA requested that CCI provide estimated data for the fugacity of the 2 main components of CNSL.

Response: CCI will provide fugacity data for cardanol and cardol estimated using a Level III fugacity model.

Health Effects

Acute oral toxicity: EPA agreed with CCI that OECD Guideline 425 should be conducted to determine the acute toxicity of CNSL. ED did not agree that this study is necessary because the range- finding study to select doses for the OECD 422 study will provide adequate high- dose toxicity data for screening level purposes.

Response: CCI agrees with ED that, in the interests of animal welfare, the acute study should not be conducted, therefore data to fill this endpoint will be derived from the OECD 422 range- finding study.

Repeat Dose/developmental/reproductive toxicity: EPA and ED agreed with CCI's plan to conduct a OECD 422 repeat dose toxicity test combined with reproductive/developmental toxi city screening tests. PCRM did not agree with this approach and stated that CCI should have made use of information presented in the Alkylphenols category submission. PCRM also stated that the situation is similar to that for closed system intermediates, where chronic testing is not necessary.

Response: CCI does not believe that CNSL is similar enough in structure either to be included in the alkylphenols category or to allow read across to data presented in the alkylphenols submission. CCI cannot guarantee how CNSL is handled in all workplaces and does not believe that the substance meets the definition of a closed system intermediate. Therefore, the OECD 422 test will be conducted.

Genetic Toxicity: EPA requested amendments to the robust summaries of these studies to clarify the composition and purity of Cardolite NC 511.

Response: The robust summaries will be modified. The composition for distilled CNSL given in the test plan is, in fact, identical to that of Cardolite NC 511.

Ecological Effects

EPA states that it believes that CNSL is not acutely toxic in the aquatic environment and that it is concerned over possible chronic effects and has suggested that a 90- day rainbow trout study be undertaken.

Response: Regarding ecological effects testing, we are voluntarily providing test data on CNSL, per the SIDS guideline as originally agreed, at considerable cost. We are not ready to commit to testing outside the original agreement.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Chris Ford
Quality Assurance Manager